DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

2107 '04 MAY 24 A8:32

Re: Genesis Neurostimulation System
Docket No. 02E-0149

MAY 20 2004

Peter Lando
Director for Intellectual Property Affairs
Hughes & Luce, L.L.P.
1717 Main Street, Suite 2800
Dallas, TX 75201

Dear Mr. Lando:

This is in regard to your letter of May 22, 2003, which asks for a redetermination of the regulatory review period for the Genesis Neurostimulation System. The regulatory review period determination was published in the *Federal Register* on March 24, 2003 (68 Fed. Reg. 14244).

Your letter addresses both the testing phase and approval phase portions of the regulatory review period determination. First, you state that the IDE referenced in the *Federal Register* notice was unrelated to the Genesis submission under section 515 of the Federal Food, Drug, and Cosmetic Act (the Act). FDA's position is that although this IDE was for a different indication, it is material to the approval of the Genesis Neurostimulation System. FDA considers all investigational exemptions for a particular product to be material to the approval of the product, regardless of any difference between the indications studied and those ultimately approved. Therefore, FDA stands by its determination, as stated in the *Federal Register* notice, that for the Genesis Neurostimulation System, the date a clinical investigation on humans was begun is August 11, 2000, which is the effective date of the first IDE.

Second, your letter requests that in determining the length of the period beginning "on the date an application was initially submitted with respect to the device under section 515 [of the Act] and ending on the date such application was approved under such Act," FDA look to the date on which your company submitted a petition under section 513(f)(3) of the Act, seeking the reclassification of your device from class III into class II. FDA disagrees with this interpretation of the computation directed by the patent law, 35 U.S.C. 156(g)(3)(B)(ii). That statute directs the government to compute the period from the date that an application under section 515 of the Act -- a PMA -- was initially submitted until the date that same application was approved. A petition for reclassification is submitted under section 513 of the Act and is not an application under section 515 of the Act. Nor was pursuit of the reclassification petition necessary in order for you to submit a PMA. Your device was not unclassified prior to the conclusion of the reclassification proceeding; the initial classification of your device was as a class III device, by operation of

section 513(f)(1) of the Act.[1] You also request that the approval phase of the regulatory review period include the period beginning with ANS' submission of the first module of the Genesis PMA to the FDA. It is FDA's position that the approval phase begins when the marketing application is complete. The final module of the Genesis PMA was submitted to the FDA on May 29, 2001. Therefore, FDA stands by its determination as stated in the *Federal Register* notice that the date the marketing application was submitted with respect to the device under section 515 of the Act is May 29, 2001.

The total length of the regulatory review period, therefore, is unchanged, and consists of 469 days. Of this time, 292 days occurred during the testing phase and 177 days occurred during the approval phase.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: The Honorable Jon Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450.

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[1] Section 513(f)(1) provides:

Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of enactment of this section, is classified in class III unless --

(A) the device --

(i) is within a type of device (I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b), or (II) which was not so introduced or delivered before such date and has been classified in class I or II, and
(ii) is substantially equivalent to another device within such type, or

(B) the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) or (3) classifying the device in class I or II.